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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/674,457 | 01/05/2001 | Anders Larsson | PL-9813 | 8539 |

26271 7590 02/03/2004
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EXAMINER

HANDY, DWAYNE K

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| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 02/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,457

Applicant(s)

LARSSON ET AL.

Examiner

Dwayne K Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-31, 33, 36 and 41-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 20, 33, 36 and 41-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Objections

1. Claims 29 and 30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 29 and 30 were previously objected to for improper form since the claims were dependent from a device, but claimed "the method of...". Applicant's amendment fixed this problem. The amended claim, however, appears to be attempting to place a limitation on the fluids to be used in the device and not the device itself. This does not further limit a device claim since the liquid is not part of the device.

Inventorship

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 20-26, 29-31, 33, 36, 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248) in view of Burns et al. (6,379,929). Kellogg et al. was cited in the previous Office Action in a 102 rejection. As stated in the previous action (paragraph 3), Kellogg teaches a microfluidic device comprised of a circular disc which contains a microfluidic network. Fluid flow is controlled in the network through the use of capillary valves based on surface tension differences. Specifically, the surface tension differences are created through the use of hydrophobic/hydrophilic junctions between sections of the microfluidic network. The

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following passage shows how Kellogg uses these surface properties for valving purposes between a reservoir and a microchannel:

(110) 2. Centrifugal rotors, microplatforms and Microsystems are also fabricated comprising material having contact angles $<90^\circ$ and other material having contact angles $>90^\circ$. **For example, using aqueous solutions a fluid reservoir may be hydrophilic (contact angle $<90^\circ$), whereas a tube or channel is fabricated from a material having a contact angle $>90^\circ$. (thereby requiring positive pressure to be applied to motivate fluid flow from the reservoir into the channel).**

Kellogg does not teach a hydrophobic section within a hydrophilic pathway as is now recited in the instant claims. Instead, Kellogg teaches an entire channel comprised of a hydrophobic material which borders a hydrophilic chamber or reservoir. This teaching was also cited by applicant in their response to the previous Office Action (page 7).

Burns et al. (6,379,929) teaches a chip based microfluidic device which also controls fluid flow in the channels through the use of areas of differing surface tensions. Burns discusses this in columns 7 and 8. Burns also shows an example in Figures 3A and 3B (described in columns 35 and 36). This embodiment of the device is described in column 35 and includes a hydrophobic region (40) which is used to stop fluid in the middle of a channel for flow control (column 8, lines 1-10). It would have been obvious to combine the hydrophobic patches from Burns with the device of Kellogg. The use of hydrophobic regions within the channel would allow for multiple valves within a channel which could be used to stop fluid flow in several places instead of at just one interface. It would also lower the energy requirement for moving liquids further down the channels

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of the microfluidic network since Kellogg teaches a channel which is *entirely* hydrophobic and must use centripetal force for driving fluids through the entire channel.

As for the limitation of a channel outlet as recited in claim 25, it would have been obvious to one of ordinary skill in the art to provide an outlet for the channels in the microfluidic network. One would provide a channel outlet toward the end of the channel to remove materials from the channel so that either the channel may be filled again, or to further process the contents of the channel.

5. Claims 27-28 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248) in view of Sheppard, Jr. et al. (6,143,247). Kellogg, as described above in paragraph 3, teaches every element of claimed 27-28 except for treating the channels to enable cell culture and treating the substrate with plasma treatment. Sheppard also teaches a circular device for detecting and quantifying particulate matter suspended in a fluid. The invention provides an integrated, affinity-binding based, analytical system comprising a platform for performing an affinity-binding based assay for specifically binding particulates including microbial cells, and a detection means for detecting the particulates specifically bound to a defined surface or chamber comprising the platform. Methods for using the analytical systems of the invention are also provided. Sheppard specifically mentions cell capturing and testing in column 4, lines 31-60. Sheppard also teaches surface modification through plasma deposition (column 16, lines 9-37) - including the use of materials that will attract and bind cellular material. It would have been obvious to one of ordinary skill in the art to

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combine the plasma coating of the cell affinity material of Sheppard with the device and methods of Kellogg. One would add the cellular material to perform capture and analysis of cellular material as taught by Sheppard. One would use the plasma coating method since it is a well-known substrate coating method which can be used to coat the cellular affinity materials of Sheppard onto a substrate.

Response to Arguments

6. Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection. In response to the Examiner's previous rejection, applicant has amended the instant claims to recite a hydrophobic section within a hydrophilic pathway. The Examiner agrees with applicant that Kellogg does not teach this feature. As noted above, Kellogg teaches a valving structure that is defined as the boundary between areas of differing surface tensions as required by the claim before it was amended. The Examiner believes, however, that the addition of the teachings from the reference "Burns" yields a teaching of microfluidic device with a hydrophobic section within a hydrophilic pathway. Burns teaches a hydrophobic region for controlling the fluid flow within a hydrophilic channel as required by the amended claims.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

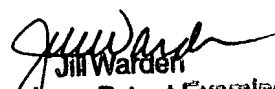
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1700.

DKH
January 22, 2004


Jill Warden
Supervisory Patent Examiner
Technology Center 1700